REMARKS

In the Office Communication, it is alleged that the application contains claims directed to 10 patentably distinct species. In response, Applicant disagrees with the characterization of Applicant's claimed invention. The restriction is hereby traversed.

Provisional Election of Species with Traverse

In response, as a formality merely to comply with 35 U.S.C. 121, Applicant provisionally elects Group I, claims 31-40 for an examination on the merits.

Arguments in Support of Traversal of Restriction

It is Applicant's position that the claims are of a single general inventive concept under PCT Rule 13.1.

A common technical feature among the Groups I-X is the culture medium comprising: a) 0.1%-90% autologous human serum, b) 0.1%-10.000% UI/ml heparin, c) 0.1%-10.000% UI/ml protamine, and d) a base culture medium including nutrients. The Examiner asserts that this common technical feature is an obvious variant of a known composition described in Xia et al., The Journal of Immunology, p. 1134, Fig. 5 (hereinafter "Xia"). However, it is respectfully submitted that the Restriction Requirement is in error for the following reasons.

Initially, the special character of the above identified technical feature in the sense of 37 CFR 1.475 is addressed. According to 37 CFR 1.475, a special technical feature is any common element that defines a contribution over the prior art. Accordingly, the culture medium described above greatly contributes to the technical advancement of the field of *isolation and expansion of cultured autologous human progenitor stem cells*. Previously (*i.e.*, before the priority date of the present application), it was technically challenging to isolate or expand autologous human stem cells in culture. However, according to the claims of the present application and thorough experimental procedures described in the present application, improved results of using the above described culture media for expanding autologous human stem cells is realized.

In addition, it is respectfully submitted that Xia provides an improper basis for the restriction. While the Examiner considers that the culture medium is an "obvious" variation of an already known culture media published in Xia, the authors of Xia use a heparin-containing

media for the differentiation of monocytes based on the premise that there are specific heparin-binding receptors on the surface. That is, Xia discloses the culture of human monocytes (which are *not* progenitor stem cells) in a medium (AIM-V) containing autologous serum (2%) with heparin (25 Ul/ml) and protamine sulphate (0.125 mg/ml). Other assays disclosed in Xia use dendritic cells (which are also *not* progranitor stem cells) to examine the effect of heparin-induced differentiation on their physiology (*i.e.*, production of IL-10 and priming of naïve CD4+ cells). Therefore, the use of heparin in Xia is related to its capacity to promote differentiation of monocytes into CD1a+ dendritic cells. Protamine sulphate, a heparin-binding protein, is used here for neutralization of heparin in order to understand the mechanisms mediating heparin-dependent differentiation. Hence, motivations to use heparin and protamine in the culture media of Xia run contrary to the motivations for using the culture media disclosed in the present application. Also, differentiation and expansion (relating to proliferation) are fundamentally opposed biological processes and, therefore, Xia strongly sets out a prejudice for the use of the culture media of the present application for cell expansion, thereby providing anything but an obviating disclosure.

Furthermore, contrary to Xia, the present application does not use heparin to manipulate cell physiology. According to the present application, heparin is used as an anticoagulant in the plasmapheresis and protamine sulphate is used to reverse anticoagulation. In this manner, the use of the serum obtained from plasmapheresis with heparin and protamine enables blending with culture media without subsequent problems during cell culture. Also, heparin is used in the culture medium instead of anticoagulants which are traditionally used during plasmapheresis. In the present application, plasmapheresis is the process of choice for obtaining autologous human serum. However, in Xia, the method for obtaining autologous human serum is not disclosed, neither is there any indication suggesting the role that heparin plays in the present application.

Accordingly, in view of the above reasons, it is respectfully submitted that the restriction is improper. It is therefore respectfully requested that the restriction requirement be withdrawn and the claims be examined on the merits.

If the Examiner disagrees, she is respectfully requested to reject the claims for the second time to allow Applicant an opportunity to petition the restriction requirement.

An earnest effort has been made to be fully responsive to the Examiner's correspondence and advance the prosecution of this case. If there are questions, the Examiner is respectfully requested to call the undersigned attorney at the number listed below.

Respectfully submitted,

Dated: April 28, 2008

By:_____
Michael J. Marcin (Reg. No. 48,198)

Fay Kaplun & Marcin, LLP
150 Broadway, Suite 702
New York, NY 10038
Tel: (212) 619-6000
Fax: (212) 619-0276